K053044

JAN 2 4 2006

510(k) Summary

Name of device:

OPTO GLOBAL Digital Fundus Camera System Model ADS 1.5

Common or usual name: Camera, Ophthalmic (AC Powered)

Classification Name:

Ophthalmic Camera (per 21 CFR.886.1120)
Device, Storage, Images, Ophthalmic (per 21 CFR.892.2010
Device, Communication, Images, Ophthalmic (per CFR 21 892.2020)

Product Code:

HKI, NFF, NFG

Submitter: OPTO Global, Inc.

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Date Prepared: 20 August 2005

Predicate Devices

Trade Name	Manufacturer	510 (k)
Visucam	Carl Zeiss Ophthalmic Systems Inc	K021787
FF450 plus Visupac System	Carl Zeiss Jena GmbH	K011877
Imagenet Digital Ophthalmic Imaging* *(Sold in the U.S. for years)	Topcon Corp	Cannot Locate
50X, 50 EX Fundus camera* *(Sold in the U.S. for years)	Topcon Corp	Cannot Locate

Intended Use

The Opto Global Digital Fundus Camera System Model ADS 1.5 is intended to be used to capture, archive, and display digital images of the eye, particularly the retina obtained through the use of an ophthalmic camera (fundus camera).

Device Description

The OPTO Global ADS 1.5 Digital Fundus Camera System is an automated imaging device used in conjunction with a digital camera that requires minimal intervention during the capture of an image. The system is simple to use and requires minimal training for a user to become proficient with the system. Like the listed predicate devices, the Opto Global Digital Fundus Camera System Model ADS 1.5 is comprised of a digital imaging camera, computer hardware, and a software platform intended to be used to store images captured by the fundus camera. Thus the Opto Global Digital Fundus Camera System Model ADS 1.5 has the same intended use and indications as the listed predicate devices.

Substantial Equivalence

The Opto Global Digital Fundus Camera System Model ADS 1.5 and the predicate devices listed all have the same intended use: to capture and archive images of the retina taken with a fundus camera. The Opto Global Digital Fundus Camera System Model ADS 1.5 and the predicate devices listed have equivalent principles of operation and technological characteristics. Each of the devices is a digital ophthalmic camera system and image storage device. The user views the patient's retina through a fundus camera. A light source is used to illuminate the retina and the fundus triggers the digital cameras to capture images of the retina. These digitized images are then archived for future use or record.

The Opto Global Digital Fundus Camera System Model ADS 1.5 and all of the listed predicate devices use, and are operated by, PC's with keyboards and a hand operated mouse. While there may be some very minor differences in types of processor (Intel Pentium IV or AMD Athelon) processors speed, and software platform, these minor differences do not raise any new issues of safety or effectiveness and do not affect the imaging capabilities of the Opto Global Digital Fundus Camera System Model ADS 1.5 or any of the predicate devices listed.

The Opto Global Digital Fundus Camera System Model ADS 1.5 and all of the predicate devices have the same basic software functions: image acquisition, storage, analysis, and retrieval. The principle differences can be found in the graphical user interface.

Most software platforms found in the predicate devices are windows based and effectively function using different screens for different functions, and drop down menus and graphic buttons to control, or perform, various tasks in the capture, archive, and recall of images.

These slight differences do not raise new or additional questions regarding safety or efficacy in the OPTO Global Digital Fundus Camera System Model ADS 1.5 or other predicate systems. OPTO Global Inc. has performed several software validation tests the results of which clearly indicate that the Opto Global Digital Fundus Camera System Model ADS 1.5 meets comparable system and software standards exhibited by the predicate devices listed.

The OPTO Global Digital Fundus Camera System Model ADS 1.5 and all of the predicate devices listed are operated in the same manner. The Ophthalmologist, or Photographer, views the patients eye through an ophthalmic camera (fundus camera) with a digital camera used to capture, manipulate and archive images using the graphical user software interface. The Opto Global Digital Fundus Camera System Model ADS 1.5 and all of the predicate devices listed use the system software to manipulate images into produce proof sheets (photo collages of the patients eye captured during the procedure) the software also carries the capabilities of printing individual images or proof sheets, view individual photos or proof sheets on the computer monitor, and to archive selected captured images onto the computers hard drive or several types of removable media such as standard CD's or DVD's.

Performance characteristics

The Opto Global Digital Fundus Camera System Model ADS 1.5 is comprised of the following components: A digital sensor head (digital camera) a computer interface circuit board (digital image capture card), and connecting cables. These components are then combined and sold together with our "OPTO Global Capture" proprietary imaging software and a computer (CPU) monitor, keyboard and mouse.

This total system with imaging software provides acquisition and hardware control capabilities used to take digital pictures of the retina which are then transferred via the digital camera and connecting cable to the computer system where they can be viewed, modified, stored or printed. The Opto Global Digital Fundus Camera System Model ADS 1.5 is intended to capture and store images of the Retina, and it is also indicated for use as an ophthalmic camera for individuals where documentation of the retina is important to follow and treat certain pathologies.

The Opto Global Digital Fundus Camera System Model ADS 1.5 software interface allows images from the fundus camera to be acquired, monitored, stored and retrieved. Imaging, focusing, and camera orientation in relation to the retina are controlled by the user. With verification and monitoring, the software allows the user to monitor, capture, and process, images thus verifying the device is operating correctly. The image viewed through the fundus camera and captured by the digital camera is then stored as individual images in a non compressed state on the hard drive of the computer to be displayed electronically as the user requires it.

Conclusion

The Opto Global Digital Fundus Camera System Model ADS 1.5 has the same intended use, indications, and very similar principals of operation to the predicate devices listed. The Opto Global Digital Fundus Camera System Model ADS 1.5 also has similar technological characteristics (hardware and software) to the predicate devices listed.

The minor differences between the Opto Global Digital Fundus Camera System Model ADS 1.5 and those of the listed predicate devices do not raise any new questions of safety or of effectiveness in comparison to the predicate devices. Thus the Opto Global Digital Fundus Camera System Model ADS 1.5 is substantially equivalent to legally marketed ophthalmic camera systems.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 24 2006

OPTO Global, Inc.
C/O Lorinda Badalian
Senior Project Engineer
Underwriters Laboratories, Inc.
455 E. Trimble Rd
San Jose, CA 95131-1230

Re: K053044
Trade/Device Name: OPTO Global Digital Fundus Camera System Model ADS 1.5
Regulation Number: 21 CFR 886.1120
Regulation Name: Ophthalmic Camera
Regulatory Class: Class II
Product Code: HKI; NFF; NFG
Dated: January 10, 2006
Received: January 11, 2006

Dear Ms. Badalian:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 827-8910. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

M. B. Eydelman, MD

Malvina B. Eydelman, M.D.
Acting Division Director
Division of Ophthalmic and Ear,
Nose and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if Known): K053044

Device Name: OPTO Global Digital Fundus Camera System Model ADS 1.5

Indications for Use :

The OPTO Global Digital Fundus Camera System Model ADS 1.5 is intended to be used to capture, archive, recall and display black and white, and color images of the retina, as well as surrounding areas, to aid in the diagnosis and monitoring of diseases of the eye that may be viewed and photographed non-invasively.

Prescription Use ✓ or Over-the-counter Use _____
(Per CFR 21 801.109)

(PLEASE DO NOT WRITE BELOW THIS LINE—CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Ophthalmic Ear,
Nose and Throat Devises

510(k) Number K053044